UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419 Master Dkt.: 1:13-md-02419-FDS
THIS DOCUMENT RELATES TO: All Actions	

NOTICE OF REVISED SUBPOENA EXHIBIT

The Plaintiffs' Steering Committee ("PSC") hereby informs the Court that, on Friday, September 27, 2013, the PSC sent the attached letter and revised subpoena exhibit to counsel for the subpoenaed clinics, doctors, and hospitals.[1]

The letter describes the PSC's previous agreement to narrow the scope of its requests (both in substance and in time). The revised exhibit reflects these accommodations.

Dated: September 30, 2013

Respectfully submitted,

/s/ Kristen Johnson Parker

Thomas M. Sobol
Kristen Johnson Parker
HAGENS BERMAN SOBOL SHAPIRO LLP
55 Cambridge Parkway, Suite 301
Cambridge, MA 02142
Telephone: (617) 482-3700
Facsimile: (617) 482-3003
tom@hbsslaw.com
kristenjp@hbsslaw.com

Plaintiffs' Lead Counsel

[1] A few subpoena recipients have apparently not retained counsel or changed counsel. The PSC will make efforts to ensure that those entities receive a copy of the attached letter and revised subpoena exhibit.

Elizabeth J. Cabraser
Mark P. Chalos
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
275 Battery Street, 29th Floor
San Francisco, CA 94111
Telephone: (415) 956-1000
Facsimile: (415) 956-1008
ecabraser@lchb.com
mchalos@lchb.com

Federal/State Liaison

Marc E. Lipton
LIPTON LAW
18930 W. 10 Mile Road
Southfield, MI 48075
Telephone: (248) 557-1688
Facsimile: (248) 557-6344
marc@liptonlawcentercom

Kim Dougherty
JANET, JENNER & SUGGS, LLC
75 Arlington St., Suite 500
Boston, MA 02116
Telephone: (617) 933-1265
kdougherty@myadvocates.com

Patrick T. Fennell
CRANDALL & KATT
366 Elm Avenue, S.W.
Roanoke, VA 24016
Telephone: (540) 342-2000
pfennel@crandalllaw.com

Mark Zamora
ZAMORA FIRM
6 Concourse Way, 22nd Floor
Atlanta, GA 30328
Telephone: (404) 451-7781
Facsimile: (404) 506-9223
marc@markzamora.com

J. Gerard Stranch, IV
Benjamin A. Gastel
BRANSETTER, STRANCH & JENNINGS PLLC
227 Second Avenue North
Nashville, TN 37201
Telephone: (615) 254-8801
Facsimile: (615) 255-5419
gerards@branstetterlaw.com

Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I, Kristen Johnson Parker, hereby certify that I caused a copy of the foregoing Notice of Revised Subpoena Exhibit to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: September 30, 2013

/s/ Kristen Johnson Parker
Kristen Johnson Parker, BBO # 667261

T 617.482.3700 F 617.482.3003

HAGENS BERMAN

Kristen Johnson Parker
HAGENS BERMAN SOBOL SHAPIRO LLP
55 CAMBRIDGE PARKWAY, SUITE 301
CAMBRIDGE, MA 02142
www.hbsslaw.com
Direct (617) 475-1961
kristenjp@hbsslaw.com

September 27, 2013

VIA EMAIL

Re: *In Re: New England Compounding Pharmacy, Inc. Products Liability Litigation*
MDL 2419; C.A. No.: 13-md-2419-FDS

Dear Subpoena Recipient:

I write on behalf of the Plaintiffs' Steering Committee ("PSC") to all clinics, doctors, and hospitals that received subpoenas from the PSC.

During the September 25, 2013 status conference on objections to the PSC's subpoenas, some subpoena recipients told the Court that they were not aware that the PSC had agreed to further limit the documents and information sought by its subpoenas. As explained below, the PSC described these accommodations in detail in submissions filed with the Court back in July.[1]

I now write to ensure that every subpoena recipient is aware of these accommodations. A copy of a revised subpoena exhibit reflecting these modifications is attached.

Background

On June 21, 2013, attorneys acting on behalf of the Plaintiffs' Steering Committee served subpoenas on clinics, doctors, and hospitals identified by the United States Centers for Disease Control and Prevention ("CDC") as having received medication from any of three recalled lots of Methylprednisolone Acetate ("MPA") from New England Compounding Pharmacy, Inc. ("NECC"). A number of subpoenas were served on additional clinics as the PSC became aware of patients who received notice that they had been exposed to contaminated NECC medication by and from clinics that were not among the CDC's Identified Clinics.

The subpoenas were virtually identical. All contained both a notice of deposition (to take the deposition of a designated Records Custodian) and a demand for production of certain documents identified in an exhibit to the subpoena.[2]

---

[1] 12-md-2419, ECF #325; ECF # 340 (Minute entry for July 18, 2013 status conference); ECF #352.

[2] Some subpoenas served on clinics in the State of Tennessee contained additional requirements in the request for production of document due to unique circumstances arising from the statutory environment in that state.

Several subpoena recipients filed objections to, or motions to quash, the subpoenas. Others raised objections informally with plaintiffs' counsel. Many of these objections are now pending before the Honorable Jennifer C. Boal.

In response to these objections, the PSC met and deliberated – both internally and with some subpoena recipients – and agreed to further refine our requests in order to minimize the burden on clinics. The specific changes to the subpoena exhibit were first reflected, in redline, in a revised subpoena exhibit attached to the PSC's July 17, 2013 Consolidated Response to Subpoena Objections as Exhibit B.[3]

In late July, the Honorable Henry J. Boroff – the judge presiding over the NECC bankruptcy – issued an order requiring customers of NECC that received products identified by the CDC as contaminated to produce a list of persons who were administered MPA from the three contaminated lots to the Trustee, the Creditors' Committee, and the Plaintiffs' Steering Committee by August 16, 2013.[4] On July 26, 2013, in response to Judge Boroff's preliminary ruling from the bench, the PSC advised Judge Saylor that we would not try to enforce the specific subpoena requests that sought the same information Judge Boroff had already ordered be produced.[5]

On August 3, 2013, the PSC wrote to subpoena objectors to inform them about Judge Boroff's order, Judge Saylor's order, and the PSC's position.

The Revised Exhibit

The PSC agreed to make three accommodations:

(i) Reduce the production of documents required pursuant to the subpoenas, including narrowing time periods and restricting certain requests to products that the CDC identified as contaminated;[6]

(ii) Forego the noticed "Records Custodian" depositions (except for unique circumstances); and

---

[3] ECF # 325.

[4] 12-19882(bankruptcy), ECF # 412.

[5] On August 1, 2013, Judge Saylor issued an order granting subpoena recipients' motions to quash to the extent that a subpoena seeks to obtain patient medical records or other patient information as to individuals who are not parties to any action presently pending in the MDL court for the purpose of providing notice to possible claimants in the bankruptcy court.

[6] http://emergency.cdc.gov/HAN/han00337.asp.

(iii) Extend the deadline for producing documents to August 15, 2013 (then the close of discovery) for those objectors who agreed to produce documents on a rolling basis.

Attached is a revised exhibit to the subpoena you were served with earlier. It reflects these accommodations described in the PSC's July filings, including the withdrawal of the request seeking patient names and contact information. This revised exhibit is identical to the version filed back in July, except that it deletes request #6 and strikes the reference to "triamcinalone" in request #2.[7]

We offer this revision in the spirit of compromise and in response to those concerns and objections raised by clinics. The revised subpoena exhibit deletes and narrows the original requests; it does not add. The PSC therefore does not intend to re-serve subpoenas on the more than 80 recipients. Our sincere hope is that this revised exhibit will resolve objections related to burden, scope, and patient privilege/privacy.

Next steps

You will be hearing from counsel tasked to follow up on outstanding subpoenas soon. But please do not hesitate to contact me or Lead Counsel Tom Sobol (tom@hbsslaw.com, 617-482-3700) directly with any questions or concerns. We are also happy to discuss the logistics of producing documents to our designated vendor.

Thanks very much.

Sincerely,

/s/ Kristen Johnson Parker
Kristen Johnson Parker
HAGENS BERMAN SOBOL SHAPIRO LLP

On Behalf of the Plaintiffs' Steering Committee

Cc: The Honorable Jennifer C. Boal

[7] Though the PSC does not expect to do so, we reserve the right to subpoena documents relating to triamcinolone if later developments in this litigation prove such discovery warranted.

Revised Exhibit __ to Subpoena

Unless otherwise noted, all requests pertain to the time period October 6, 2010 through October 6, 2012

1. *MPA and Triamcinolone:* Any and all documents and/or electronically stored information ("ESI") reflecting, and/or related in any way whatsoever to, the procurement of methylprednisolone acetate ("MPA") and Triamcinolone from New England Compounding Pharmacy, Inc. ("NECP") that the CDC has identified as contaminated, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of steroid preparation, the cost you paid for the steroid preparation, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased. Also including account information, prescriptions submitted to NECP, prescription order forms, NECP charges for MPA (before and after any discounts applied) or any other compounded steroid medication encompassed by this request.

2. *Equivalents to MPA:* Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of MPA, or its generic or name-brand equivalent, or any other NECC compounded medication identified as contaminated by the CDC, from any producer, compounding facility or manufacturer other than NECP, since 1/1/2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of the product, the cost you paid for the product, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased.

3. *Cardioplegic solution:* Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of cardioplegic solution from NECP that the CDC has identified as contaminated including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of cardioplegic solution, the cost you paid for the cardioplegic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for cardioplegic solution (before and after any discounts applied).

4. *Betamethasone:* Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of Betamethasone from NECP that the CDC has identified as contaminated, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of ophthalmic solution, the cost you paid for the ophthalmic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for opthalmic solution (before and after any discounts applied).

Author
Deleted: A

Author
Deleted: any other injectable steroid preparations compounded steroid medication

Author
Deleted: during the two-year period immediately preceding October 6, 2012,

Author
Deleted: .

Author
Deleted: *and Triamcinolone*

Author
Deleted: any equivalent medication to

Author
Deleted: or Triamcinolone

Author
Deleted: since October 6, 2007

Author
Deleted: during the two-year period immediately preceding October 6, 2012,

Author
Deleted: ophthalmic

Author
Deleted: solution

Author
Deleted: during the two-year period immediately preceding October 6, 2012

5.

6.

7. *Communications with NECP:* Any and all documents and/or ESI reflecting or containing communications (written or otherwise) between NAME OF TARGET HEALTHCARE PROVIDER ("Healthcare Provider"), its employees, principals, partners, and/or agents, and NECP, its employees and/or agents, during the two-year period immediately preceding October 6, 2012, including, but not limited to, any complaints or adverse event reports made to NECP by the Healthcare Provider.

8. *Information about NECP's qualifications:* Any and all documents and/or ESI reflecting or containing information obtained by the Healthcare Provider, its employees and/or agents, regarding NECP, including without limitation of the foregoing, NECP's qualifications, certifications or accreditations, or lack thereof, regulatory compliance, lack of regulatory compliance, operations, enforcement actions, suitability for conducting its business, legal actions and/or warnings, brochures, policies and procedures, ordering and delivery information company overviews, standard operating procedures, executive summaries, attachments A, B or others (relating to HIPAA, NECP policies and procedures, or other information).

9. *Communications received about fitness of NECP's products:* Any and all documents and/or ESI reflecting or containing information obtained by, or communications received by, the Healthcare Provider, its employees and/or agents, concerning the fitness of any products purchased or obtained from NECP for their intended use, for the medical products determined by the CDC to be contaminated, including but not limited to any environmental testing results, microbiology reports or certificates of analysis.

10. *Information received from governmental entities:* Any and all documents and/or ESI reflecting or containing information obtained by, or sent to, the Healthcare Provider, its employees and/agents, from the Centers for Disease Control and Prevention, the Federal Food and Drug Administration, and/or any other Federal, state or local regulatory agency, concerning the fitness of any products manufactured, compounded or produced by NECP for their intended purpose.

12. *Marketing information:* Any and all documents and/or ESI reflecting or containing marketing information from NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.

13. *Contracts with NECP:* Any and all documents and/or ESI reflecting or containing agreements, contracts and/or warranties between the Healthcare Provider and NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.

14. *Recall notices received:* Any and all documents and/or ESI reflecting or containing recall notices received by the Healthcare Provider pertaining to products produced by NECP, including without limitation of the foregoing, the date, time and manner of receipt of the

Author

Deleted: Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of preservative-free saline solution from NECP that the CDC has identified as contaminated during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of saline solution, the cost you paid for the saline solution, applicable warranties, shelf life, expiration dates, and requirement and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for preservative-free saline solution (before and after any discounts applied).

Author

Deleted: *Identification of exposed patients:* Any and all documents and/or ESI reflecting, and/or related to, the identification of each and every patient that was administered an NECP product that the CDC has identified as contaminated, or that have previously been compiled in response to a request from the Centers for Disease Control and Prevention, the Federal Food and Drug Administration, and/or any other Federal, state or local regulatory agency, any Grand Jury Subpoena, or any other governmental entity, during the two-year period immediately preceding October 6, 2012, including patient name, address, date of birth, identification of product administered, and date product was administered.

Author

Deleted: during the two-year period immediately preceding October 6, 2012

Author

Deleted: medications

Author

Deleted: 11. . Any and all documents and/or ESI reflecting or containing communications between the Healthcare Provider and any federal or state agency (including, but not limited to state licensing authorities, the Food and Drug Administration, and the Centers for Disease Control and Prevention) in connection with the procurement of products from any compounding pharmacy. ... [1]

recall notices, the specific person or persons within the Healthcare Provider who received the notice, and the substance of the notice.

15. *Communications responding to recall notices:* Any and all documents and/or ESI reflecting or containing communications made or issued by the Healthcare Provider, its employees and/or agents, in response to any recall notice regarding NECP products, including without limitation of the foregoing, the date, time and manner of transmission of the communication, the person(s) to which the communication was directed, and the person at the Healthcare Provider who made or delivered the communication.

16. *Compliance with USP:* Any and all documents regarding any investigation or inquiry the Healthcare Provider performed related to attempts by NECP to comply with United States Pharmacopeia – National Formulary, Chapter 797 (USP – NF General Chapter 797, entitled "Pharmaceutical Compounding – Sterile Preparations").

17. *Insurance policies:* Any and all policies of insurance, including without limitation of the foregoing, professional liability, malpractice, products liability, general liability, and comprehensive or umbrella policies, issued to the Healthcare Provider and/or its principal officers and directors and/or any physician working for or on behalf of the Healthcare Provider, for the policy periods covering any use of NECP medical products identified as contaminated by the CDC.

18. *Articles of incorporation:* Articles of Incorporation and/or By-Laws applicable to the Healthcare Provider for calendar years 2011, 2012 and 2013.

Author

Deleted: including calendar years 2011, 2012 and 2013

Author

Deleted: 19. Any and all documents and/or ESI reflecting or containing the names, addresses and positions (President, Vice-President, Director, etc.) within the Healthcare Provider of all officers and directors of the Healthcare Provider during the calendar years 2011, 2012 and 2013. ... [2]

Revised Exhibit __ to Subpoena

Unless otherwise noted, all requests pertain to the time period October 6, 2010 through October 6, 2012

1. *MPA and Triamcinolone:* Any and all documents and/or electronically stored information ("ESI") reflecting, and/or related in any way whatsoever to, the procurement of methylprednisolone acetate ("MPA") and Triamcinolone from New England Compounding Pharmacy, Inc. ("NECP") that the CDC has identified as contaminated including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of steroid preparation, the cost you paid for the steroid preparation, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased. Also including account information, prescriptions submitted to NECP, prescription order forms, NECP charges for MPA (before and after any discounts applied) or any other compounded steroid medication encompassed by this request.

2. *Equivalents to MPA:* Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of MPA, or its generic or name-brand equivalent, or any other NECC compounded medication identified as contaminated by the CDC, from any producer, compounding facility or manufacturer other than NECP, since 1/1/2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of the product, the cost you paid for the product, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased.

3. *Cardioplegic solution:* Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of cardioplegic solution from NECP that the CDC has identified as contaminated including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of cardioplegic solution, the cost you paid for the cardioplegic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for cardioplegic solution (before and after any discounts applied).

4. *Betamethasone:* Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of Betamethasone from NECP that the CDC has identified as contaminated, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of ophthalmic solution, the cost you paid for the ophthalmic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for opthalmic solution (before and after any discounts applied).

7. *Communications with NECP:* Any and all documents and/or ESI reflecting or containing communications (written or otherwise) between NAME OF TARGET HEALTHCARE PROVIDER ("Healthcare Provider"), its employees, principals, partners, and/or agents, and NECP, its employees and/or agents, during the two-year period immediately preceding October 6, 2012, including, but not limited to, any complaints or adverse event reports made to NECP by the Healthcare Provider.

8. *Information about NECP's qualifications:* Any and all documents and/or ESI reflecting or containing information obtained by the Healthcare Provider, its employees and/or agents, regarding NECP, including without limitation of the foregoing, NECP's qualifications, certifications or accreditations, or lack thereof, regulatory compliance, lack of regulatory compliance, operations, enforcement actions, suitability for conducting its business, legal actions and/or warnings, brochures, policies and procedures, ordering and delivery information company overviews, standard operating procedures, executive summaries, attachments A, B or others (relating to HIPAA, NECP policies and procedures, or other information).

9. *Communications received about fitness of NECP's products:* Any and all documents and/or ESI reflecting or containing information obtained by, or communications received by, the Healthcare Provider, its employees and/or agents, concerning the fitness of any products purchased or obtained from NECP for their intended use, for the medical products determined by the CDC to be contaminated, including but not limited to any environmental testing results, microbiology reports or certificates of analysis.

10. *Information received from governmental entities:* Any and all documents and/or ESI reflecting or containing information obtained by, or sent to, the Healthcare Provider, its employees and/agents, from the Centers for Disease Control and Prevention, the Federal Food and Drug Administration, and/or any other Federal, state or local regulatory agency, concerning the fitness of any products manufactured, compounded or produced by NECP for their intended purpose.

12. *Marketing information:* Any and all documents and/or ESI reflecting or containing marketing information from NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.

13. *Contracts with NECP:* Any and all documents and/or ESI reflecting or containing agreements, contracts and/or warranties between the Healthcare Provider and NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.

14. *Recall notices received:* Any and all documents and/or ESI reflecting or containing recall notices received by the Healthcare Provider pertaining to products produced by NECP, including without limitation of the foregoing, the date, time and manner of receipt of the recall notices, the specific person or persons within the Healthcare Provider who received the notice, and the substance of the notice.

15. *Communications responding to recall notices:* Any and all documents and/or ESI reflecting or containing communications made or issued by the Healthcare Provider, its employees and/or agents, in response to any recall notice regarding NECP products, including without limitation of the foregoing, the date, time and manner of transmission of the communication, the person(s) to which the communication was directed, and the person at the Healthcare Provider who made or delivered the communication.

16. *Compliance with USP:* Any and all documents regarding any investigation or inquiry the Healthcare Provider performed related to attempts by NECP to comply with United States Pharmacopeia – National Formulary, Chapter 797 (USP – NF General Chapter 797, entitled "Pharmaceutical Compounding – Sterile Preparations").

17. *Insurance policies:* Any and all policies of insurance, including without limitation of the foregoing, professional liability, malpractice, products liability, general liability, and comprehensive or umbrella policies, issued to the Healthcare Provider and/or its principal officers and directors and/or any physician working for or on behalf of the Healthcare Provider, for the policy periods covering any use of NECP medical products identified as contaminated by the CDC.

18. *Articles of incorporation:* Articles of Incorporation and/or By-Laws applicable to the Healthcare Provider for calendar years 2011, 2012 and 2013.